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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,248	12/21/2001	Gregory P. Kushla	BAI-007CPACN	9410

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,248	KUSHLA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for The Extension of Time and Request for Continued Examination filed 03/25/04, and Amendment filed 11/25/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/25/04 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-34 of U.S. Patent No. 6,348,216 ('216). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '216 claims a pharmaceutical composition comprising a tablet material comprised of ibuprofen, hydrocodone bitartrate (narcotic analgesic), colloidal silicon dioxide, filler, disintegrant, binder, starch, and lubricant. The blend of granule and extragranule is found in claims 2 and 34. The composition is substantially free of lactose is found in claims 1 and 2. Therefore, one of ordinary skill in the art would expect the same tablet composition results from the use of the instant invention given the claims of '216. There are no unusual and/or unexpected results, which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of '216, which set out a similar tablet composition using the same materials and amounts as claimed herein.

Claims 1 and 3-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,599,531 ('531). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '531 claims a pharmaceutical composition comprising a tablet material comprised of ibuprofen, hydrocodone bitartrate (narcotic analgesic), colloidal silicon dioxide, filler, disintegrant, binder, starch, and lubricant. The blend of granule and extragranule is found in claims 2 and 34. The composition is substantially free of lactose is found in claims 1 and 2. Therefore, one of

ordinary skill in the art would expect the same tablet composition results from the use of the instant invention given the claims of '216. There are no unusual and/or unexpected results, which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of '216, which set out a similar tablet composition using the same materials and amounts as claimed herein.

It is noted that the claims of both, the '216 and '531 patents are product-by-process, per se, however, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, claims 1 and 3-8 of the instant application anticipate the claims of the '216 and '531 patents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lomen EP 0 068 838 A1.

Lomen teaches a composition comprising combination of narcotic analgesic and ibuprofen or flurbiprofen (see abstract). The composition can be prepared in powder, granule, tablet or capsule oral dosage form (page 2, lines 24-30). The oral dosage form

further comprises diluent, lubricant, and binder (page 2, lines 31 through page 3, lines 1-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lomen EP 0 068 838 A1, and Haas US 4,859,704.

Lomen is relied upon for the reason stated above. Lomen does not teach the claimed filler, lubricant, and disintegrant agents.

Haas teaches a composition comprising ibuprofen in conjunction or combination with other medications such as narcotics (column 1, lines 15-27). Haas also teaches the use of silicon dioxide, binder, sodium starch glycolate, lubricant, and filler in an oral dosage tablet (example 2). Haas is silent as to the claimed amount of silicon dioxide, however, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to prepare the oral

dosage form of Lomen using the excipients and carriers taught by Haas, because the references teach the advantageous results in the use of solid dosage form comprising combination of ibuprofen and narcotic with known oral dosage carrier useful in pharmaceutical art.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lomen EP 0 068 838 A1, and Elger et al. US 4,844,907.

Lomen is relied upon for the reasons stated above. The reference is silent as to the teachings of the claimed filler, lubricant, and disintegrant agents.

Elger teaches tablet composition comprising combination ibuprofen and narcotic analgesic (abstract and examples). Elger teaches tablet composition can be made by wet granulating the active ingredients and excipients, including microcrystalline cellulose, starch, binder, glidants, anti-adherents, and disintegrants (columns 3-5). Thus, it would have been obvious for one of ordinary skill in the art to prepare the oral dosage form of Lomen using the excipients and carriers taught by Elger, because the references teach the advantageous results in the use of solid dosage form comprising combination of ibuprofen and narcotic with known oral dosage carrier useful in pharmaceutical art.

The examiner notes that Elger does not teach the amounts of actives, excipients and relative proportions of the granule and extra granule material. However, generally, differences in concentration/amount will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

concentration/amount is critical. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Accordingly, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine suitable amounts of actives and excipients with the expectation of at least similar result, because Elger obtains the same result desired by the applicant, *e.g.*, compressed tablet having good stability, disintegration times and dissolution rates.

Response to Arguments

Applicant's arguments filed 11/25/03 have been fully considered but they are not persuasive.

Applicant argues that Lomen does not teach or suggest a pharmaceutical composition comprising granule and extragranule material, wherein the extragranule material comprises an excipient. In contrast, Lomen only describes compositions comprising a granule and a lubricant. Contrary to the applicant's argument, Lomen teaches a tablet composition comprising mixture of granulated active ingredients (ibuprofen and narcotic analgesic); diluent, such as lactose or starch; and binder, including corn syrup, gelating solution, methylcellulose solution or acacia mucilage (page 3, 3rd paragraph). Applicant's claim does not define excipient. Accordingly, Lomen does teach a pharmaceutical composition comprising granule and extragranule material (diluent, binder, and/or lubricant), and therefore, anticipated the claimed invention. Thus, the 102(b) rejection of claims 1 and 3 by Lomen is maintained.

Applicant argues that Lomen and Haas do not teach or suggest compositions which are substantially free of lactose. In contrast, each of the tablets described by Lomen contain a substantial amount of lactose. The examiner is unable to determine the critical effect in the present/absent of lactose between the "substantially free [amount]" of the claimed invention, and the "substantial amount" present in the composition of Lomen. The burden is shifted to applicant to provide data establishing detrimental effects in the present of "substantial amount" of lactose in the composition of Lomen and Haas.

Applicant argues that Elger does not teach compositions comprise extra-granule material or colloidal silicon dioxide. However, the broad term "extra-granule material" permits materials, such as binder, lubricant, carrier, and excipient. Colloidal silicon dioxide is a well-known glidant/lubricant in pharmaceutical art, and therefore, it would have been obvious to the skilled artisan to, by routine experimentation select colloidal silicon dioxide as a glidant in view of the teaching of Elger.

Applicant argues that Elger does not teach ibuprofen and narcotic in one phase, and therefore would not have been obvious to combine. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is further noted that obviousness can only be established

by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Elger is relied upon for the teachings of the well-known excipients and carriers in an oral solid dosage form.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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